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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,186	07/28/2000	Paul Chinn	P 037003 0280721	2673

7590

01/05/2004

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

628,186

Applicant(s)

CHINN

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 9/22/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-16, 18, 49-61 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-16, 18, 49-61 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Amendment of 9/22/03 has been entered. Claims 1-16, 18 and 49-61 are pending and under examination.

The amendment has overcome previously stated issues as follows:

The rejection of claim 1 under 35 USC 112, 2nd paragraph.

The prior art rejection based upon Mather et al. Note teachings in Figs. 1 and 3 and at pg. 311, col. 2, 2nd full para.

The prior art rejection based upon Richardson et al.

The prior art rejection based upon Chinol et al. See pg. 1468, col. 1, 1st para.

The prior art rejection based upon Ultee et al. Ultee et al do not exemplify Re labeling; thus one could not determine from their disclosure what level of radiolabel incorporation and specific activity would be achieved with Re.

The following rejections of record are maintained or modified as follows:

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 18, 70% is unclear as to what it is relative to.

Applicant has urged (pg. 7) that "binding specificity" is art understood to represent the percentage of antibody that binds target antigen relative to binding of the same antibody to non-specific antigen. The examiner disagrees since, in a perfect situation, all of the antibody would bind to the target antigen and none to the non-specific antigen; in such case, the relative binding ratio would be calculated with a zero in the denominator, resulting in the ridiculous "binding specificity" of infinity. Examiner notes that Mather et al calculate their "immunoreactivity" (which could be reasonably interpreted as being the same as "binding specificity") as the proportion of added radioactivity that bound to the cells (bearing target antigen); see pg. 308,

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para. spanning cols. 1-2. The examiner could also envision "binding specificity" as being the ratio of binding activity for specific antigen in the radiolabeled antibody preparation compared to such activity in the antibody preparation prior to labeling. Applicant must point to where the specification precisely defines or exemplifies such a calculation, with a showing of what values are in the numerator and denominator, rather than vaguely arguing what the art recognizes.

Applicant's arguments filed 9/22/03 have been fully considered but they are not persuasive.

Applicant's amendment has necessitated the following new ground(s) of rejection.

Claims 1-16, 18 and 49-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended/new claims contain new matter.

In claim 1, "radiochemical purity" is new matter. Applicant points to pgs. 17-18 and original claim 17 for support; however, these recite "radioincorporation" not "radiochemical purity". Since it is not clear on the record that these two terms are equivalent, claims are considered to recite new matter.

In new claims 49-51 "about" is new matter. Applicant urges Table 3, which recites 3, 5 and 10 minutes, provides support; but the examiner fails to see how this supports "about", since nothing in the Table indicates that there were deviations from these specifically recited incubation times.

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In new claims 52-55 "at least about" is new matter. Applicant urges Tables 1-3 and 6-7 support. While various percent incorporations close to the recited percentages may be found in these Tables, the examiner fails to see where the precise recited percentages are to be found; for example, where is 96.0% or 98.0% in these Tables? Further, the examiner sees no basis for reciting "about"; for example, if 96.3% in Table 1 supports 96%, then the examiner finds no value in any of the Tables that is lower, in order to support "about" in conjunction with "96%".

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 703-308-3976. The examiner can normally be reached on Mon-Thu from 8:00 to 5:30. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 703-308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Typed 12/30/03

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
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